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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,158	12/05/2001	Wu-Bo Li	0942.4750003	3737

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EXAMINER
LOEB, BRONWEN

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,158	LI ET AL.	
	Examiner	Art Unit	
	Bronwen M. Loeb	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 January 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This action is in response to the amendment filed 13 January 2003 in which claims 1-27 were cancelled and new claims 28-48 were presented.

Claims 28-48 are pending.

Drawings

1. The corrected or substitute drawings were received on 13 January 2003. These drawings are acceptable.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Response to Amendment

3. The rejection of claims 1-27 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been rendered moot in view of Applicant's cancellation of claims 1-27.

The rejection of claims 1, 5, 7-12 and 25-27 under 35 U.S.C. §102(b) as being anticipated by Mullis et al (USP 4,800,159; IDS reference AA1), has been rendered moot in view of Applicant's cancellation of claims 1-27.

The rejection of claims 1, 2, 5-8, 10-19, 22, 23 and 25-27 under 35 U.S.C. §103(a) as being unpatentable over Pruitt (Gene (1988) 66:121-134; IDS reference AT6) in view of Wieland et al (Proc. Natl. Acad. Sci. USA (1990) 87:2720-2724; IDS reference AR11) and Rubenstein et al (Nucleic Acids Research (1990) 18:4833-4842; ISD reference AT7), has been rendered moot in view of Applicant's cancellation of claims 1-27.

The rejection of claims 3, 4, 21, 22 and 24 under 35 U.S.C. §103 as being unpatentable over Pruitt in view of Wieland et al (Wieland), and Rubenstein et al (Rubenstein) as applied to claims 1, 2, 5-8, 10-19, 23 and 25-27 above, and further in view of Vandeyar et al. (Gene (1988) 65:129-133; ISD reference AR10), has been rendered moot in view of Applicant's cancellation of claims 1-27.

The rejection of claim 9 under 35 U.S.C. §103 as being unpatentable over Pruitt in view of Wieland et al (Wieland), and Rubenstein et al (Rubenstein) as applied to claims 1, 2, 5-8, 10-19, 23 and 25-27 above, and further in view of Welcher et al.

(Nucleic Acids Research (1986) 14:10027-10044; IDS reference AS11), has been rendered moot in view of Applicant's cancellation of claims 1-27.

The rejection of claim 20 under 35 U.S.C. §103 as being unpatentable over Pruitt in view of Wieland et al (Wieland), and Rubenstein et al (Rubenstein) as applied to claims 1, 2, 5-8, 10-19, 21, and 25-27 above, and further in view of Rashtchian et al. (Analytical Biochemistry (1992) 206:91-97; IDS reference AR7), has been rendered moot in view of Applicant's cancellation of claims 1-27.

The rejection of claims 2, 6, 13-19 and 23 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 8-13 and 17 of U.S. Patent No. 5,500,356 has been rendered moot in view of Applicant's cancellation of claims 1-27.

The rejection of claims 1, 2, 6, 7 and 13-17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 20, 23-28, 40 and 41 of U.S. Patent No. 5,759,778 has been rendered moot in view of Applicant's cancellation of claims 1-27.

The provisional rejection of claims 2 and 6 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 28 and 43 of copending Application No. 09/018,989 has been rendered moot in view of Applicant's cancellation of claims 1-27.

4. New grounds of rejection, necessitated by Applicant's amendment, are set forth below.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 28-33, 38-43 and 46 are rejected under 35 U.S.C. §102(b) as being anticipated by Radding et al (USP 4,888,274; IDS reference AB1).

Radding et al teach enriching for desired DNA molecules using haptenylated probes coated with RecA protein to hybridize to circular or linear double-stranded DNA molecules. Use of probes coated with RecA promotes homologous pairing, thus minimizing random hybridization. The hybridized complexes are isolated using, for instance, a solid support comprising a molecule that binds the hapten on the probe. The isolated complexes are transformed into bacteria for further selection or propagation. Biotin is a preferred hapten. Probes containing biotin covalently linked to their 3' end are taught (biotinylation by terminal transferase). Molecules taught that bind biotin include avidin and stretavidin; these are bound to solid supports such as agarose to allow for isolation by column separation. The targeted double-stranded DNA molecules may be sequences from a cDNA library or mixtures of DNA from genomic DNA. See entire document, particular Figure 2B, col. 1, lines 56-58, col. 3, lines 4-58,

col. 5, line 44-col. 7, line 34, col. 11, lines 17-23, col. 11, line 58-col. 14, line 2 and Examples VII and VIII.

7. Claims 28, 30, 31, 33, 38, 39, 41, 43, 46 and 47 are rejected under 35 U.S.C. §102(b) as being anticipated by Abe (JP 4-108384; citations are to the provided English translation).

Abe teaches a method of taking double-stranded DNA and making it single stranded, mixing a biotinylated probe with the single-stranded DNA molecules to form hybridized complexes, isolating the complexes using magnetic beads coated with streptavidin, using PCR to make the isolated molecules double stranded and transforming E. coli with the double-stranded DNA molecules. Application Example 1 teaches using testic RNA to generate a mixture of double-stranded DNA for use in the method. See entire document, especially Figure 1, p. 4 and pp. 6-8.

8. Claims 28, 30, 31, 33, 38, 39, 41, 43, 46 and 47 are rejected under 35 U.S.C. §102(b) as being anticipated by Tagle et al (Nature (1993) 361:751-753; IDS reference AT12).

Tagle et al teach enriching for desired sequences by hybridizing biotinylated probes to a cDNA library, isolating the hybridized complex by capturing them on paramagnetic streptavidin beads and washing off the unbound DNA, and subcloning the DNA so isolated to create a region-specific library. As one of ordinary skill in the art knows, "subcloning" involves transforming a host organism to propagate the recombinant DNA. See entire document, particularly Figure 1.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not , commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(e), (f) or (g) prior art under 35 U.S.C. §103(a).

11. Claims 28-33, 38-43, 46 and 48 are rejected under 35 U.S.C. §103(a) as being unpatentable over Radding et al in view of either Florkiewicz (USP 6,028,058) or Knappe et al (USP 5,989,867).

Radding et al is applied as above to claims 28-33, 38-43 and 46. Radding et al does not teach using a probe comprising a degenerate sequence.

Florkiewicz teaches use of hybridization of a degenerate probe to a library as a standard recombinant DNA cloning procedure. See col. 7, lines 66-col. 8, line 29.

Knappe et al teach screening libraries by hybridization with degenerate probes to identify clones in different species of a desired nucleic acid. See col. 29, lines 10-21.

At the time the invention was made, it would have been prima facie obvious to use degenerate probes and primers in methods for enriching or recovering a desired target nucleic acid as these were well known in the art, as shown by Florkiewicz or Knappe et al. One of ordinary skill in the art would have been motivated to use degenerate probes or primers in order to isolate sequences related to a known sequence, such as other members of a gene family or sequences having point mutations, etc.

12. Claims 28-33 and 38-46 are rejected under 35 U.S.C. §103(a) as being unpatentable over Radding et al in view of Symons (USP 4,898,951).

Radding et al is applied as above to claims 28-33, 38-43 and 46. Radding et al does not teach using an antibody against biotin as a molecule for binding biotin and isolating the hybridized complex.

Symons teaches anti-biotin antibodies are art-recognized equivalents to avidin or streptavidin for binding to biotin. See col. 14, lines 10-15.

At the time the invention was made, it would have been prima facie obvious to one of ordinary skill in the art to use any equivalent to avidin or streptavidin, including antibodies against biotin and functional fragments thereof, for binding to biotin in any method. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). See also MPEP 2144.06.

13. Claims 28-43 and 46 are rejected under 35 U.S.C. §103(a) as being unpatentable over Radding et al in view of Sambrook et al (Molecular Cloning A Laboratory Manual" Second Edition, Cold Spring Harbor Laboratory Press, Cold Spring Harbor 1989; copy of this reference not provided as it is a standard reference in any lab utilizing molecular biology techniques).

Radding et al is applied as above to claims 28-33, 38-43 and 46. Radding et al does not teach target nucleic acids which are single-stranded plasmids, single-stranded cosmids or single-stranded phagemids.

Sambrook et al teach constructing genomic DNA libraries in cosmid vectors, plasmid vectors and in phagemids such as single-stranded filamentous bacteriophage vectors.

At the time the invention was made, it would have been prima facie obvious to one of ordinary skill in the art to use any of the well known types of genomic DNA libraries taught by Sambrook et al in the method of enriching for a desired target sequence as taught by Radding. One of ordinary skill in the art would have been motivated to do so depending on the requirements of the genomic library (i.e. ease of bacterial transformation or transduction, and size of inserts). Making double-stranded DNA single stranded for hybridization is also prima facie obvious as this would contribute to improved hybridization (since the probe would not have to displace a complementary strand) and complex recovery.

Conclusion

Claims 28-48 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 11:00 AM to 7:30 PM. A phone message left at this number will be responded to as

soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

March 22, 2003

JAMES KETTER
PRIMARY EXAMINER